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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Thomas C Kienzle III

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EXAMINER

ABRAHAM, SALIEU M

ART UNIT

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3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,092	Applicant(s) KIENZLE, THOMAS C	
	Examiner SALIEU M. ABRAHAM	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the claims (1 to 8 and 41) to group I in the reply filed on October 14, 2009 is acknowledged. The traversal is on the ground(s) that search and examination of all the claims in the instant application can be made without serious burden. This is not found persuasive because the prior restriction requirement filed September 29, 2009 clearly establishes each of the four claim groups to be independent or distinct and have a separate classification in the art as evidenced by the different/separate class in which each of the groups is classified (see item 2 below). Specifically, group I, classified in class 606, subclass 130, is directed to multimodal tracking in an operating theater such as a multi-camera system for tracking a medical device/tool ex vivo (i.e. before an abdominal incision is made); group II, classified in class 128, subclass 699, encompasses bone localization apparatus and protocols such as are used in an integrated surgical anchor/localizer device that can be anchored into bone; group III, classified in class 600, subclass 427, encompasses in vivo surgical navigation tracking systems such as a stereo static imaging system for determining the position of a surgical probe within a patient's head and group IV, classified in class 702, subclass 155, encompasses range sensing systems such as those employing acoustic energy to track body motion (cf. US 7395181).

Meeting both, distinctness and separate classification criteria have been held to clearly establish grounds for meeting the examination serious burden requirement (see MPEP 808.02). Furthermore, restriction may be made after the first action on the merits

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as restriction is proper at any time before final action and as soon as the need for a proper requirement develops (see MPEP 811 and 37 CFR 1.142(a)). The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1– 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,235,038 to Hunter (**Hunter**).

In Reference to Claim 1

Hunter teaches:

A system for tracking the position of an instrument relative to an area of interest (i.e. the surgical operating area; see abstract) comprised of a single or plurality of fixators (translational devices; see fig. 1) to include first (20), second (60, 80 or 100) or more (abstract, col. 5, lines 2-15) that can be secured to various points along an area of interest (fig. 1 and col. 5, lines 16-52), the fixators all being configured to carry interchangeable first and second localizing devices (optical or electromagnetic transmitters/receivers; see col. 5, lines 52-57) and whereby a third localizing device positioned proximate a third point along the area of interest (col. 5, lines 2-15) such that *it is capable of communicating* with other localizing devices directly or indirectly such that its position relative to the other localizing device(s) is known (col. 5, lines 9-15).

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In Reference to Claim 2

Hunter teaches the system of claim 1, wherein the first localizing device is an electromagnetic transmitter and the second and third localizing devices are electromagnetic receivers. (col. 6, lines 39-61)

In Reference to Claim 3

Hunter teaches the system of claim 1, wherein the first, second, and third localizing device are emitters for use in an optical tracking system. (col. 5, lines 53-58).

In Reference to Claim 4

Hunter teaches the system of claim 1, further comprising a computer system that monitors the communications between said first, second, and third localizing devices and calculates their relative positions. (col. 5, lines 25-26)

In Reference to Claim 5

Hunter teaches the system of claim 1, wherein additional localizing devices may be positioned about said area of interest. (col.5, lines 7-9)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 6 - 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,235,038 to Hunter (**Hunter**) in view of US Pat. No. 6,827,723 to Carson (**Carson**).

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In Reference to Claims 6 - 8

Hunter has been shown to teach all claim limitations to include image acquisition using imaging systems/modalities that commonly employ apparatus such as a C-arm (col. 1, lines 39-42), a fixator configured to carry an electromagnetic (EM) transmitter and receiver and fixator securement at different sites/locations as needed (e.g. a matter of design choice; see fig.1 and col. 5, lines 16-58). However, Hunter does not specifically teach a C-arm having an imaging device and fixator securement by bone screws or connectable strap to a patient.

Carson discloses computer-based intra-operative systems and methods for obtaining anatomical images as well as registering, navigating and tracking target anatomical sites, surgical instruments and/or implants (abstract). Carson's invention uses a C-arm with an imaging device (fig. 3) along with arthroscopic knee fixators (figs. 2-3) to which EM transceivers can be attached (14) for image registration, and surgical implement navigation and tracking (cols. 10, lines 35-67 and 11, lines 1-12). It would be obvious to one of ordinary skill in the art to employ trackable fixators as fiducials in the anatomical area being evaluated as a matter of design or study choice. It would be further obvious to one of ordinary skill that various fixator securement means could be employed in the surgical environment in order to ensure system accuracy for registration and tracking (col.) and that screw and connectable strap securements are commonly used in the art (see Carson, col. 8, lines 10-12 and art of record < US Pat. No. 6,161,032> to Acker, see fig. 1 and col. 6, lines 53-56) as necessitated by the anatomical area under study and user choice. Lastly, it would be obvious to one of ordinary skill in the art to include C-arm apparatus and imaging device of Carson with the system of Hunter in order to facilitate intraoperative imaging as taught by Carson.

6. Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of US Pat. No. 6,887,245 to Kienzle (**Kienzle**).

Carson discloses a method where first and second fixators (fig. 1, elements 12 and 26) carrying corresponding first and second localizing devices (14) **are** proximate to first and second areas of interest (AOI's; fig. 1, elements 12 and 26). Carson further

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discloses an imager with third localization device (fig. 1, imager and 14), image acquisition of an AOI (cols. 3, lines 46-51 and 12, lines 22-29), determining relative first, second and third localizing device positions and calculating differences between first and second positions of stationary (first and third) localization devices relative to the moving (second) localization device (i.e. a surgical implement or tool; see fig. 1, and cols. 11, lines 53-67 to 12, lines 1-56). However, Carson does not disclose determining and indicating an error if the positions of localization sensors were not within a certain range of each other in order to better determine the relative positions of two areas of interest.

Kienzle discloses a surgical drill for use with computer assisted surgery (abstract). The drill can have EM markers/sensors (transmitters or receivers) attached to it for navigation and tracking (abstract, fig. 1, elements 101 and 111). The drill further includes sensor-derived alignment and error reporting features to alert medical personnel in case the device is positioned or oriented improperly for surgery as (col. 6, lines 5-33).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the positional error detection scheme of Kienzle in the method of Carson in order to facilitate more accurate navigation and tracking of a surgical implement during surgery as taught by Kienzle.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barnett et al., Cinquin et al., Foley et al., Guthrie et al., Hunter et al., Melkent et al., Messner et al. and Schulz et al. have been included because they all teach the use of diagnostic imaging methods and systems which make use of electromagnetic energy for position and orientation tracking of areas of interest in vivo similar in scope to applicant's proposed invention.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 9:30 am - 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1/27/10 SA

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768